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REMARKS

This Amendment is being submitted with a Request for Continued Examination (RCE) and constitutes the required submission. This Amendment is responsive to the Final Office Action mailed May 21, 2007. Applicants have amended claims 1, 19, 24, 25, 27-30, 33 and 38; canceled claim 2; and added new claims 40-42. Claims 3, 12-17, 23 and 26 were previously canceled. Claims 1, 4-11, 18-22, 24, 25 and 27- 42 are now pending.

All pending claims have been amended to clarify that one or more electrodes are deployed on or implanted within cellular muscle tissue of the prostate gland. In the Final Office Action, the Examiner explained that the former claim language (e.g., stimulation of *tissue* of the prostrate) could be reasonably interpreted as stimulation of nerve tissue that innervates the prostate. The current claim amendment should now clarify that the claimed invention is directed to methods, systems and implanted medical devices that use one or more electrodes deployed on or implanted within cellular muscle tissue of the prostate gland. Support for these claim amendments can be found in paragraph **[0028]**.

Rejection for Obviousness-type Double Patenting:

The Examiner provisionally rejected claims 1, 3, 5-11, 18, 24, 26, 30, 32 and 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-11, 14-16, 22-28, 33-37, 40, 53, 56-58, 61-62, 65-67, 70-73, 78-82, 85-89, and 99-102 of copending Application No. 10/441,784.

Applicants note the provisional status of this rejection. Accordingly, Applicants will address this issue if and when the rejection is formally applied. In reserving comment at this time, Applicants in no way admit or acquiesce in the propriety of this rejection.

In the Office Action, the Examiner indicated that the current *provisional* double patenting rejection is already a formal application of the double patenting rejection. These comments are inapposite. A provisional double patenting rejection is not formally applied unless and until the copending application actually issues into a patent. If the present application issues into a patent prior to the copending application, the provisional double patenting rejection does not need to be addressed in the present application. In other words, any double patenting concerns only need to be addressed in the present application if the copending application actually issues into a patent.

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Otherwise, any double patenting concerns will be addressed in the copending application, not the current application.

Accordingly, the provisional nature of the double patenting rejection does not require any response or Terminal Disclaimer by Applicants unless or until the rejection is formally applied, i.e., unless or until the provisional nature of the double patenting rejection is removed due to issuance of the copending application prior to issuance of the present application.

Claim Rejections Under 35 U.S.C. § 102 and § 103

In the Final Office Action, the Examiner advanced a variety of different rejections, and provided many responses to Applicants' previous arguments. Applicant thanks the Examiner for the thoughtful detail provided in the Final Office Action. However, Applicants do not acquiesce to any of the rejections or arguments, and believes that the arguments advanced in the previous response are still applicable.

Applicants address each of the independent claims in greater detail below, but have focused the current arguments on specific features of Applicants' claims that Applicants believe to be lacking from the applied prior art. In addition, Applicants have addressed some specific prior art references that Applicants believes are being misinterpreted by the Examiner relative to the features recited in Applicants' claims.

Independent claim 1

Independent claim 1 recites a method of providing medical therapy to a patient. The method comprises delivering one or more therapeutic stimulation pulses to tissue of a prostate gland via an implantable medical device. In addition, claim 1 requires that the therapeutic stimulation pulses delivered to the tissue of the prostrate gland are defined to treat sexual dysfunction by one or more of the following: causing erection, causing ejaculation, preventing ejaculation, preventing premature ejaculation, and causing erection and preventing premature ejaculation In this Amendment, Applicants have clarified claim 1 to require that the implantable medical device includes one or more electrodes that are deployed on or implanted within cellular muscle tissue of the prostate gland.

None of the applied references discloses or suggests stimulation of cellular muscle tissue of the prostrate gland specifically for treatment of sexual dysfunction. Instead, the applied prior art teaches stimulation of specific nerves (such as the pelvic splanchnic nerves or the pudendal nerves) to treat conditions of impotence, or prostate gland stimulation for treatment of benign prostatic hyperplasia (BPH).

In the Final Office Action, the Examiner explained that the former claim language (e.g., stimulation of *tissue* of the prostrate) could be reasonably interpreted as stimulation of nerve tissue that innervates the prostate. The amendment to claim 1 should now clarify that claim 1 is directed to a method that uses one or more electrodes deployed on or implanted within cellular muscle tissue of the prostate gland. Support for this claim amendment can be found in paragraph **[0028]**.

While the applied prior art may suggest nerve stimulation for the treatment of sexual dysfunction, nothing suggests the stimulation of muscular tissue of the prostate gland via electrodes disposed on or implanted within cellular muscle tissue of the prostate gland. Furthermore, while the applied prior art may suggest prostate gland stimulation for treatment of BPH, nothing suggests stimulation by electrodes disposed on or implanted within cellular muscle tissue of the prostate gland via therapeutic stimulation pulses defined to cause erection, cause ejaculation, prevent ejaculation, prevent premature ejaculation, or cause erection and prevent premature ejaculation, as required by claim 1. Furthermore, the Examiner has failed to provide any proof that the prostate gland stimulation suggested in the prior art (e.g., the "low level direct current provided to the prostate gland in USPN 6,901,294 (hereafter Whitehurst '294)) would inherently cause erection, cause ejaculation, prevent ejaculation, prevent premature ejaculation, or cause erection and prevent premature ejaculation, as required by claim 1.

In view of the amendment to claim 1, and remarks above, Applicants request the Examiner's reconsideration and allowance of claim 1 and its respective dependent claims.

Independent claims 19, 24, 28 and 33

Independent claims 19, 24, 28 and 33 all concern prostate gland stimulation to change the fiber structure of the prostate gland. Such techniques may, for example, be useful in treating benign prostatic hyperplasia (BPH). Claims 19 and 33 recite methods of prostate gland

stimulation, whereas claims 24 and 28 recite implantable medical devices that perform prostate gland stimulation.

Like claim 1, each of claims 19, 24, 28 and 33 has been amended to clarify that one or more electrodes are deployed on or implanted within cellular muscle tissue of the prostate gland. These claim amendments should help to clarify Applicants' inventions relative to the applied prior art. Claim 28 has also been amended to clarify that this claim is specifically directed to an *implanted* medical device, not an *implantable* medical device, which should address any inherency concerns that the Examiner may have.

Each of claims 19, 24, 28 and 33 specifically requires delivery of a training sequence that defines a first pulse train and a second pulse train, wherein the first pulse train and the second pulse train are each delivered over time periods on an order of a week. According to claims 19, 24, 28 and 33, the second pulse train (which lasts on the order of a week) is delivered after the first pulse train (which also lasts on the order of a week). The second pulse train includes more pulses per unit time than the first pulse train.

Using this technique, the fiber structure of the prostate gland can be changed in a manner that can remedy effects of benign prostatic hyperplasia (BPH). For example, the prostate gland may become more compliant and thereby remedy effects of BPH.

Applicants respectfully traverse all pending rejections of claims 19, 24, 28 and 33 to the extent such rejections may be considered applicable to the amended claims. Nothing in the applied prior art even remotely suggests the delivery of training sequences of pulses to the prostrate gland via electrodes disposed on or implanted within the cellular muscular tissue of the prostate gland.

Again, claims 19, 24, 28 and 33 recite delivery of a first pulse train and a second pulse train, wherein the first pulse train and the second pulse train are each delivered over time periods on an order of a week, and wherein the second pulse train includes more pulses per unit time than the first pulse train. Nothing in the applied prior art even remotely suggests such features.

For these features of Applicants claims (i.e., delivery of a first pulse train and a second pulse train wherein the second pulse train includes more pulses per unit time than the first pulse train), the Examiner has cited Krakovsky (5,454,840) (hereafter Krakovsky '840). Krakovsky '840, however, has nothing to do with the delivery of training sequences of pulses that change the

fibrous structure. Instead, Krakovsky '840 discloses the delivery of stimulation pulses over the course of a sexual encounter that lasts 5-20 minutes.

The Examiner recognized that none of the applied references suggests the delivery of first and second pulse trains that last on the order of one week. However, the Examiner argued that the period associated with the delivery of a pulse train is a "result effective variable," and that a person of ordinary skill in the art would have modified the period associated with such sequences of Krakovsky '840 (which last a couple minutes or less) to define sequences that last on the order of a week. Applicants respectfully submit that the Examiner's argument is flawed insofar as the "result" that is achieved according to the teaching of Krakovsky '840 is erection, emission and ejaculation over the course of a sexual encounter. Any notion that a person of ordinary skill in the art would have modified these sequences of Krakovsky '840 to last on the order of a week is incorrect, as no sexual encounter lasts even remotely that long. Furthermore, any notion that a person of ordinary skill in the art would have used sequences of Krakovsky '840 (designed for sexual encounters) to provide for treatment of BPH is nothing more than conjecture.

In the Office Action, the Examiner stated that "it has been firmly established in the case law that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges of a 'result effective variable' involves only routine skill in the art." In this case, however, the Examiner has not even demonstrated that the period associated with the delivery of a pulse train is a "result effective variable" as defined by Applicants claims. Therefore, even if the cases cited by the Examiner are legitimate law[1], the Examiner has not even attempted to address whether this law is applicable to the present case insofar as the Examiner has not even attempted to show that the prior art recognizes the period associated with the delivery of a pulse train as a result effective variable. Furthermore, Applicants claims are concerned with the result of changing the fibrous structure of the prostate gland, whereas the desired result in Krakovsky '840 is erection, emission and ejaculation over the course of one sexual encounter.

In line with the case law relied upon by the Examiner[2], it is well-established that a particular parameter must first be recognized as a result-effective variable, i.e., a variable that

[1] *In re Alter* and *In re Boesch* are both cases handed down prior to the creation of the Federal Circuit
[2] *In re Alter* and *In re Boesch*

achieves a recognized result, before any determination of optimization might be characterized as routine experimentation. The applied prior art makes no mention of training sequences, much less teach that time periods for the first and second pulse trains are result-effective variables that can affect training results to the prostate gland. Instead, desired result in Krakovsky '840 is erection, emission and ejaculation over the course of a sexual encounter. The Examiner's statement that training sequences of first and second pulse trains on the order of a week are "result effective variables" finds absolutely no support from the evidentiary record. No reasonable interpretation of the prior art would lead to a conclusion that a person of ordinary skill in the art would modify the teaching of Krakovsky '840 to provide pulse trains that last on the order of a week, as no sexual encounter lasts this long.

Contrary to the Examiner's conclusions, nothing in any of the applied prior art teaches or suggests that the timing of any training sequence is result effective. Indeed, the applied prior art does not even teach the use of training sequences for prostate gland simulation, much less provide any suggestion that the timing of sequences can effect the result of changing the fibrous structure of the prostate gland, as required by Applicants' claims. Again, the Examiner's statement that training sequences of first and second pulse trains on the order of a week are result effective variables finds absolutely no support from the evidentiary record and appears to be the Examiner's conjecture. The pulses provided by Krakovsky '840 over a 5-20 minute sexual encounter would never be extended to last on the order of a week.

Applicants respectfully request the Examiner's reconsideration of independent claims 19, 24, 28 and 33, and allowance of such claims (and the respective dependent claims) over the prior art of record.

Claims 30 and 38

Claim 30 recites a system comprising an implanted medical device that delivers stimulation pulses to a prostate gland, and an agent pump that delivers agents to the prostate gland, wherein the implanted medical device and agent pump are programmed to deliver the stimulation pulses and the agents to the prostate gland in a complementary fashion.

Claim 38 recites an implanted medical device comprising a stimulator that delivers stimulation pulses to a prostate gland, and an agent pump that delivers agents to the prostate

gland, wherein the stimulator and agent pump are programmed to deliver the stimulation pulses and the agents to the prostate gland in a complimentary fashion.

Like claim 1, claims 30 and 38 have also been amended to clarify that the implanted medical devices include one or more electrodes that are deployed on or implanted within cellular muscle tissue of the prostate gland. These claim amendments should help to clarify Applicants' inventions relative to the applied prior art.

In the final Office Action, the Examiner stated that "any manner of delivering both an agent and electrical stimulation can be considered complimentary." On this basis, the Examiner argued that the term complimentary does not further limit scope of Applicants' claims.

In an attempt to address the Examiner's concerns regarding the meaning of the term complimentary, Applicants have amended claims 30 and 38 to require that the stimulation pulses and the agents are delivered to the prostate gland in a complimentary fashion such that the stimulation pulses trigger the agents or the agents improve the effect of the stimulation pulses. This should help clarify and limit the meaning of the term complimentary in a manner that will now require the Examiner to give this term patentable consideration. These amendments are supported in Applicants' original disclosure in paragraph **[0056]**. New claim 40 further requires the stimulator and agent pump to be programmed to deliver the stimulation pulses and the agents to the prostate gland simultaneously, which is also supported in paragraph **[0056]**.

Notwithstanding these claim amendments, Applicants also request the Examiner to consider the other arguments that Applicants have advanced with respect to claims 30 and 38. Namely, that none of the applied references discloses or suggests the delivery of stimulation pulses and agents to the prostate gland, much less the delivery of stimulation pulses and agents to the prostrate gland in a complimentary fashion.

Applicants respectfully submit that the present rejections of claim 30 and 38 both rely on misinterpretations of Krakovsky '840 and Whitehurst (USPN 6,885,895) (hereafter Whitehurst '895) relative to the features recited in Applicants' claims.

Krakovsky '840 teaches stimulation of nerves rather than stimulation of the prostate gland via electrodes that are disposed on or implanted in cellular muscular tissue of the prostate gland, as required by Applicants claims. Furthermore, for drug delivery, Krakovsky '840 teaches the delivery of drugs to a patient's penis, not a patient's prostate gland. Krakovsky '840 fails to

teach simulation to the prostate gland (in the manner recited by Applicants' claims) and fails to suggest the delivery of agents to the prostrate gland. Accordingly, Krakovsky '840 clearly fails to disclose or suggest delivery of stimulation pulses and agents to the prostate gland in a complimentary fashion such that the stimulation pulses trigger the agents or the agents improve the effect of the stimulation pulses

Whitehurst '895, like Krakovsky '840 does not disclose or suggest a device that is programmed to deliver the stimulation pulses and the agents to the prostate gland in a complimentary fashion, as required by claims 30 and 38. The cited passages of Whitehurst '895, for example, describe the delivery of agents "to the penis and/or its arterial supply," which is not the same as the delivery of agents to the prostate gland, much less the delivery of the stimulation pulses and the agents to the prostate gland in a complimentary fashion such that the stimulation pulses trigger the agents or the agents improve the effect of the stimulation pulses, as required by claims 30 and 38.

In short, the Examiner has failed to identify any prior art that delivers stimulation and agents to a patient's prostate gland, much less a device that delivers stimulation and agents to a patient's prostate gland in a complimentary fashion such that the stimulation pulses trigger the agents or the agents improve the effect of the stimulation pulses, as required by claims 30 and 38.

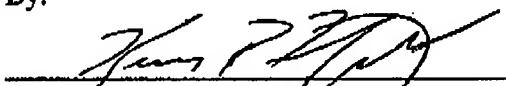
New Claims 41 and 42

New claims 41 and 42 are very similar to claims 24 and 25, and should be patentable for at least the reasons addressed above. New claims 41 and 42 differ from claims 24 and 25 in that new claims 41 and 42 recite an implantable medical device rather than an implanted medical device.

CONCLUSION

All claims in this application are in condition for allowance. In view of the claim amendments and foregoing arguments, Applicants respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: Aug. 21, 2007

By: 

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Kelly Patrick Fitzgerald
Reg. No.: 46,326